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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/674,456

09/30/2003

Ralph N. Martins

530531-2001

5975

20999 7590 10/05/2009
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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

10/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/674,456	Applicant(s) MARTINS, RALPH N.	
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 1998.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-36,38,47 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-36,38 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 27-36,38,47 and 48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/7/09 has been entered.

2. Newly submitted claim 48 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: peptides are composed of amino acid residues, which are structurally and functionally distinct from the nucleotides that make up polynucleotides, and therefore, would constitute an undue burden on the Examiner to search and examine these art recognized different group (i.e., Class/subclass 530/327; versus Class/subclass 536/23.1 for the nonelected polynucleotide of claim 48.)

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 48 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The rejection of claim 38 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the cancellation of this claim.

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4. The rejection of claims 27-36 & 38 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn due to either the amendment or cancellation of the claims.

5. Applicant's arguments filed 6/25/09 & 8/7/09 have been fully considered but they are not deemed to be fully persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 47 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for similar reasons made of record in Paper NOs: 20081218 & 20090504, and as follows. **This is a new matter rejection.**

No proper antecedent basis nor conception in context with that describe within the specification at the time of filing the instant application is apparent for the recitation of “a deletion functional variant... which is **at least 12 amino acids in length...**”; thereby, constituting new matter.

It should be noted that paragraph numbers are not presented in the copy of the specification filed with the USPTO. It is suggested that Applicant indicate by page and line number where such basis exists.

8. Claims 27-36 & 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 200711130, 20081218 & 20090504, and as follows. **This remains a written description rejection for the “functional variants thereof”.**

As previously made of record, there is no identification of any particular portion of the structure that must be conserved, which is required for binding to A β or to inhibit SOD activity or copper binding ability, in order to show any minimum correlation between structure and the recited functional language. Thus, Applicants still do not reasonably demonstrate possession of a representative number of the 80% sequence identity genus claimed.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Thus, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus because one skilled in the art cannot structurally visualize any functional generic candidate peptide (i.e., as it relates to the recited % identity), or amino acid sequences thereof, except for SEQ ID NO: 3. In summary, an invitation for others to discover a representative

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number of species, in order to reasonably extrapolate to the claimed genus, with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics does not equate to possession of the claimed genus of peptides, because one skilled in the art cannot reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of polypeptides encompassed by the claims, and for the reasons previously made of record. Thus, the written description requirements under 35 U.S.C. 112, first paragraph are not met.; consistent with that held by the courts in *Vas-Cath Inc. v. Mahurkar*, *Fiers v. Revel*, *Fiddes v. Baird* and *Univ. California v. Eli Lilly and Co* previously made of record. See also MPEP 2163.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes/

Primary Examiner, Art Unit 1649

September 21, 2009